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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/425,289	10/25/1999	John Luke Toner	NIDN-72124	9341

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AMERSHAM HEALTH
IP DEPARTMENT
101 CARNEGIE CENTER
PRINCETON, NJ 08540-6231

EXAMINER	
HARTLEY, MICHAEL G	

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 04/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/425,289	TONER ET AL.	
	Examiner	Art Unit	
	Michael G. Hartley	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *4-6 and 38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4-6 and 38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/27/2204 has been entered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 4-6 and 38 are rejected under 35 U.S.C. 102(b) as being anticipated by Tsuru (US Pat. 5,055,307).

Tsuru discloses a method of embolus therapy (i.e., vascular embolization treatment, see column 3, lines 27-30 and column 4, lines 40) comprising administering a composition comprising particles of hydroxyapatite having a size of 5 to 1000 um. The method further includes diagnostic imaging of the particles, see abstract and column 5, lines 36+. The particles are porous particles of hydroxyapatite, which encapsulate an X-ray contrast medium, sodium iothalamate, or even encapsulate calcium phosphate in the particles (which is also within the scope of a diagnostically effective compound), see example 1. The particles or granules of the hydroxyapatite in example 1 are the same as the particles claimed and exemplified in the present application (i.e., example 14, page 34). Also the embolic particles disclosed by Tsuru are prepared by a method which is the same as set forth in the instant application, i.e., hydroxyapatite particles are prepared (note, these particles are porous) and the particles are mixed with a solution of a water soluble x-ray contrast agent (e.g., iohexol, as in example 14 of the application, and sodium iothalamate in the prior art, see example 1 of Tsuru), so that the contrast agent enters the pores

of the hydroxyapatite particles and is encapsulated therein. Thus, the particles disclosed by Tsuru are the same as the particles being claimed. Also, Tsuru discloses a method of embolus therapy with subsequent imaging using said particles, as set forth above. The limitation of claim 4 is an inherent property of an embolization method, as this is the desired effect of embolization.

Response to Arguments

Applicant's arguments filed 2/25/2004 have been considered but are not found persuasive.

Applicant asserts that Tsuru fails to disclose methods that use solid water-soluble particles encapsulated by a non-polymeric matrix.

This argument is not seen relevant, as this is not in line with the claim language. In the claims the particles are not encapsulated by the matrix, but the matrix makes up the particles, which encapsulate the non-radioactive diagnostically effective compound.

Applicant asserts that Tsuru does not disclose a non-radioactive compound encapsulated in a non-polymeric matrix.

This is not found persuasive because the particles are the same as claimed, hydroxyapatite, which encapsulate an diagnostically effective compound, such as, an X-ray contrast agent, as well as, calcium phosphate, which would be within the broad scope of "a non-radioactive diagnostically effective" compound, as such a metal would enhance MRI, as well as, X-ray.

Applicant asserts that Tsuru is directed to therapeutic methods rather than diagnostic detection.

This is not found persuasive because Tsuru clearly discloses a method of embolus therapy which uses embolytic particles which include a contrast agent for imaging purposes, as is seen clearly by the abstract which states imaging by x-ray or ultrasound imaging. The use of contrast agents is exemplified in example 1, namely, iothalamate, which is an iodinated contrast agent, as claimed. Also, this argument is not seen, as the instant claims are drawn to "A method of embolus therapy" as set forth in claim 38.

Response to Arguments

Applicant's arguments with respect to claims 38 and 4-6 have been considered but are moot in view of the following new ground(s) of rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 38 and 4-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 38 is confusing because in that it states that the particles consist essentially of "a non-radioactive diagnostically effective compound" and "further comprises an iodinated contrast agent, MRI active agent or ultrasound contrast agent." It is confusing because it is unclear if the second recitation is defining the "diagnostically effective compound" or is in addition thereto (e.g., "further comprising).

The dependent claims fall therewith.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 38 and 4-6 are rejected under 35 U.S.C. 102(a, e) as being anticipated by Morrison (US 5,827,531).

Morrison discloses a method of embolus therapy comprising administering vesicles which encapsulating a non-radioactive diagnostically effective compound, which is a radiocontrast medium, see abstract and Figure 1. Note the instant claims do not limit the size of the vesicles, but only the particles. The claims uses Markush terminology to define what particles contain, ending with "and" then the claims states "or vesicles" which is not part of the Markush group used to define the vesicles. Thus, the vesicles are not limited to size or being of a non-polymeric particulate matrix. However, Morrison discloses vesicles having the size range as claimed, see column 9, lines 13+. Further, claims 5-6 do not limit the claims specifically being a non-polymeric matrix or a hydroxyapatite, but only limit the polymeric matrix thereto. These claims still encompass situations wherein the composition may comprise vesicles. Claim 4 does not contain an addition step and the composition of Morrison is therapeutically effective.

Claims 38 and 4-6 are rejected under 35 U.S.C. 102(a, e) as being anticipated by Unger (US 5,585,112).

Unger discloses a method of embolus therapy comprising administering vesicles which encapsulating a non-radioactive diagnostically effective compound, which is a ultrasound agent, see abstract, Figure 10 and column 27, lines 6-9. Note the instant claims do not limit the size of the vesicles, but only the particles. The claims uses Markush terminology to define what particles contain, ending with "and" then the claims states "or vesicles" which is not part of the Markush group used to define the vesicles. Thus, the vesicles are not limited to size or being of a non-polymeric particulate matrix. However, Unger discloses vesicles having a size range that encompasses that as claimed, see column 27, lines 6-9. Further, claims 5-6 do not limit the claims specifically being a non-polymeric matrix or a hydroxyapatite, but only limit the polymeric matrix thereto. These claims still encompass situations wherein the composition may comprise vesicles. Claim 4 does not contain an addition step and the composition of Unger is therapeutically effective.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 38 and 4-6 rejected under 35 U.S.C. 103(a) as being unpatentable over Unger (US 5,585,112) in view of Tsuru (5,055,307).

Unger discloses a method of embolus therapy comprising administering vesicles which encapsulating a non-radioactive diagnostically effective compound, which is a ultrasound agent, see abstract, Figure 10 and column 27, lines 6-9. Unger teaches that the vesicles are under 200 um, but fails to disclose the size range as claimed.

Tsuru teaches a method of embolus therapy using particles and teaches that particles having a size of 10-100 um are especially preferred, see column 3, lines 27+.

It would have been obvious to one of ordinary skill in the art to have optimized the size of the microparticles disclosed by Unger to be within the claimed size range because Unger teaches a size range of the particles for embolus therapy that encompass the claimed range and it is known in the art that a range with a lower limit, as claimed, i.e., 10 um, is an especially preferred range for embolus therapy, as shown by Tsuru.

Conclusion

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael G. Hartley whose telephone number is (571) 272-0616. The examiner can normally be reached on M-F, 7:30-5, off alternative Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael G. Hartley
Primary Examiner
Art Unit 1616

4/15/2004